RESEARCH DOCUMENTATION REQUIREMENTS and GUIDELINES

1. OBJECTIVES:

a) To ensure appropriate and accurate documentation is performed when conducting human subjects research at the Atlanta VA Health Care System (AVAHCS).
b) To describe how to document research visits.
c) To describe how to remove a note or addendum entered erroneously

2. RESPONSIBILITIES:

a) Investigators and research staff are responsible for promptly documenting each research encounter/visit with research subjects in either the Computerized Patient Record System (CPRS) or a paper research record.
b) Investigators are responsible for day-to-day supervision of their staff to ensure documentation is done properly and accurately.

3. PROCEDURES:

a) Research staff must be research credentialed before being granted access to CPRS.
b) Research and Development Office designee will submit request to IT for assignment of CPRS profile as appropriate.
c) Research staff should receive CPRS access and training prior to engaging with VA research subjects. Contact the Clinical Studies Center Manager for information.

4. CPRS DOCUMENTATION:

a) Creating a CPRS consent note and progress note(s) is required for all research subjects (Veterans or non-Veterans) **who receive research procedures or interventions** as inpatients or outpatients at VA medical facilities **that are either used in or may impact the medical care** of the research subject. Document research encounter/visit in CPRS within 72 hours of each encounter/visit.
    i. Examples:
        - Investigational drug studies
        - Investigational device studies
        - Use of surveys or other interventions that may provoke undue stress or anxiety
        - Diagnostic tests and clinical procedures. For example:
            1. Specimens processed by AVAHCS laboratories
            2. Colonoscopies
            3. Radiology procedures (X-rays, CTs, PET scans, etc.)
            4. Pulmonary Function tests
            5. Bronchoscopies
            6. Electrocardiograms
            7. Muscle biopsies

b) Documentation in CPRS is also permitted (but is not required) for research encounters/visits where the research subject does not receive research procedures or interventions that do not impact medical care.

c) The CPRS clinic location named “ATL Research-Study” should be used to document visits for studies not impacting hospital services. If the project does impact hospital services, a research clinic may need to be created. See “Procedure for Setting up Research Clinics in CPRS” located on the AVAHCS research website and contact the Clinical Studies Center for assistance.

d) Select “Historical Visit” box when creating CPRS research notes. This helps prevent subjects from getting billed for research services.

e) Research note “templates” have been created and must be used for documenting research visits in CPRS. Please refer to the “Research Note Titles & Templates” list posted on the AVAHCS research website.

f) The consent process must be documented by the research staff member who obtained the research consent. A research consent template must be used. Please contact the Clinical Studies Center Manager for situations when this is not feasible.

g) If a **non-veteran** is using a hospital service as part of the research study, then a CPRS record must be created so research encounters/visits may be documented (if required) and orders for procedures or tests may be entered in CPRS.

- Email the Eligibility Office according to the information below to enter a non-veteran in the CPRS system and to create a CPRS record.
  - **Subject**: RESEARCH VET
  - **To**: VHAATGEligibility@va.gov and copy Christine.mcrae@va.gov

  and provide the following **required** information:

  - State that non-veteran is an AVAHCS research participant
  - Full name
  - Date of birth
  - Full Social security number
  - Mailing address (optional)

- All non-veterans **must** receive the “VHA Notice of Privacy Practices (NOPP)” at the time of the first research visit. Refer to the “Notice of Privacy for Non-Veterans” policy located on the AVAHCS research website.

h) Removing Erroneously Entered Notes and Addendums

- Retracted notes or addendums in CPRS are deleted from the medical record but are removed from general view for most CPRS users. Retracted notes are re-generated if the record is required in legal matters.
- To retract a note: Author adds addendum to the incorrect CPRS note and must include:
  - Request for Retraction
  - Reason for the retraction
  - Direct the viewer to disregard its contents
  - Author signs the addendum
  - Email HIMS Team via VISTA to remove the content in CPRS
- To retract an addendum: Author adds another addendum including:
  - Specify the addendum to be retracted including date & time of the addendum

    - Reason for the retraction
    - Author signs the addendum
    - Email HIMS Team via VISTA to remove the content in CPRS
- Additional documentation is provided on the VA Human Research Website

5. RESEARCH RECORD (PAPER) DOCUMENTATION:

a) Documentation of the research encounter in a paper record is required if a CPRS note has not been created. Documentation in a paper research record must be created to document every VA research visit (face-to-face or telephone visits, regardless of where they occur).

b) There are sample note templates available on the AVAHCS Research website that show what the minimum requirements are for documenting research visits. Use of the research template is encouraged to include and document all required study visit information but is not required if all the required data points are included.
For example: A non-veteran is enrolled in a research study and he attends four research visits. Four separate research notes are required to be documented in the subject's research binder, one note for each encounter. No notes would need to be entered into CPRS.